**42 CFR Part 493.1200**
**Quality Assessment Plan Elements**

Written policies and procedures to monitor, assess and, when indicated, correct problems identified in the laboratory systems to include:

**General Laboratory Systems 493.1230**

Confidentiality
Complaint investigation
Communication
Personnel competency
Proficiency testing (PT)
Accuracy verification if no commercial PT is available or non-regulated analyte
Specimen identification (2 unique IDs) and integrity (proper type and condition)
Review effectiveness of corrective action

**Preanalytical Laboratory Systems 493.1240**

Test Request
Specimen submission, handling, labeling and referral
Review effectiveness of corrective action

**Analytical Laboratory Systems 493.1250**

Procedure Manual 493.1251
Test systems, equipment, instruments, reagents, media, materials and supplies
Establish and verify method performance
Preventive Maintenance and Function Checks
Calibration and Calibration Verification
Quality Control
Comparison of test results
Corrective Actions
Test Records
Review effectiveness of corrective action

**Postanalytical Laboratory Systems 493.1290**

Test Report
Alert values
Reference: lab report handling
Review effectiveness of corrective action

**QA Review**

Periodic review of monitors for each topic are documented and signed by the lab director.
Review effectiveness of corrective action
**Documentation** of all activities